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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,381	03/15/2004	Iddys D. Figueroa	200401494-1	3173

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HEWLETT-PACKARD COMPANY
Intellectual Property Administration
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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/801,381	Applicant(s) FIGUEROA ET AL.	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 29-34 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-3, 6-8, 29-30, 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Voss et al. (4,322,449), as cited by Applicant.

Examiner maintains the rejection of claims 1-3 and 6-8 of the previous office action.

Regarding the newly-added limitation of claim 3 requiring sufficient spacing to avoid coalescing, Voss' method of creating spaced, discrete dots sufficiently spaces the dots.

Newly-added claims 29 and 34 are added to this rejection for the same reasons that Voss is applied to claim 1. Voss' control over various parameters will inherently achieve the dissolution rate and surface-to-mass ratio, as outlined in the Response to Arguments section bellow.

Claim 30 is added to this rejection for the same reasons as claim 2.

Claim 32 is added to this rejection for the same reasons as claim 3.

The substrate of Voss is ingestible (Examples).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 9-10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss.

Examiner maintains the rejection of claims 9-10 of the previous office action.

Regarding claim 31, now added to this rejection, as necessitated by amendment, it is Examiner's position that in the creation of letters or other desired geometric patterns, Voss will desirably select a second dot to fully overlap a first dot to create a larger dot in a given location. It would have been within the skill of an ordinary artisan to "fully" overlap one dot with another if a larger "ink" spot is needed to create a letter, such as in, for example, dotting an "i".

3. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, as applied above, in view of Voges (5,894,841).

Examiner maintains the rejection of the previous office action.

Response to Arguments

4. Applicant's arguments filed 12/20/2005 have been fully considered but they are not persuasive.

Applicant argues that Voss does not disclose selection of desired dot locations and does not consider any relationship between dot placement and dissolution rate of an active substance (or between dot placement and surface-to-mass ratio of the resulting dots).

Examiner disagrees.

As outlined previously, Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern. A desired

pattern of dots indicates a decision was made to select a specific pattern and location of dots.

Voss teaches the control of various parameters, such as dots/second, volume/drop, number of ejection strokes, etc. Examiner maintains that controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently provide control over the dissolution rate and also the surface-to-mass ratio. The precise nature of Voss' printing technique yields such control, which is imperative to safe dosing of bioactive agents. Applicant has provided no evidence that such parameters do not inherently control the dissolution rate. In fact, Applicant's instant specification states that the geometric surface area (i.e., size) or volume of the dots affects dissolution rate (p. 8, p. 10). Applicant states on p. 13 and on p. 20 that application parameters such as drop size, firing frequency (dots/second), drop spacing, and deposition patterns are all set based on a target dissolution rate. Therefore, it remains Examiner's position that Voss' control of dots/second, pattern of dots, etc. will inherently control the dissolution rate in the same way that Applicant teaches his dissolution rate is controlled by the same parameters. Likewise, spacing of dots inherently impacts the surface-to-mass ratio (greater overlap yields lower surface-to-mass ratios because there is more "ink" mass in a relative surface area), which inherently impacts the dissolution rate. When dosing a patient, the amount of therapeutic agent, in addition to the rate at which the dose is administered, are factors considered by a physician.

Applicant argues that Voss does not sufficiently space the dots.

Examiner notes that Voss teaches spacing discrete dots.

Applicant argues that there is no motivation to create a standard deviation in dot spacing of less than 15% and requests Examiner to provide such motivation.

As outlined in the previous office action, Voss goes to great lengths to discuss the precision, uniformity, and reproducibility of the dot sizes, dosages, and concentrations he applies. Because a plate of nozzles may be used in a fixed arrangement, the dots formed should always be spaced the same, i.e., with a deviation approaching zero percent. It would have been obvious to an ordinary artisan wishing to achieve uniformity and precision in dosing to select and maintain a spacing that is consistent from dot to dot. While achieving perfect uniformity is impossible, Voss' teachings clearly direct one of ordinary skill in the art to precisely space the dots with *no standard deviation*, i.e., with a deviation approaching 0%, which would be less than 15%. Voss creates dosage zones on his ingestible substrate with specific dosage ratios. Incorrect spacing would yield a zone with too many or too few dosage dots, leading to dosage error. Likewise, in creating letters, another embodiment of Voss, a uniform spacing of the dots which create the letters would be necessary to yield letters with smooth lines (letters made of dots with varying spacing would be thicker in some areas).

Applicant argues against the combination of Voges with Voss because the substrates and purpose of each is different.

Examiner notes that Voges was cited merely to teach that inkjet printing may be performed by either piezoelectric ejection elements or thermal ejection elements.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Mondays & on Tuesday and Wednesday afternoons.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'J K Michener', is positioned above the printed name.

Jennifer Michener
Primary Examiner
Art Unit 1762
March 5, 2006